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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1646	

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DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,873	PELED ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *1-52 and 56-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

The present application was filed containing a power of attorney to Sol Sheinbein and Martin Moynihan. A correspondence address was supplied for Martin Moynihan on 11/2/2005.

Sol Sheinbein was excluded from practice before the Patent and Trademark Office (Office). The Office does not communicate with attorneys or agents who have been suspended or excluded from practice.

As a correspondence address, this Office action is being mailed to the other practitioner of record at his/her last known address as listed on the register of patent attorneys and agents. To ensure that a copy of this Office action is received in a timely manner to allow for a timely reply, a copy of the Office action is being mailed directly to the address of the inventor first named in the declaration or oath. Any reply by applicant(s) should be by way of the remaining practitioner(s) of record and should include a new correspondence address.

Election/Restrictions

1. Applicant's election of Group V, claims 56-58, in the reply filed on 8/7/2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. In the supplemental response filed on 9/13/2006, the Applicants noted that Group V, as set forth in the requirement for restriction mailed on 6/6/2006, is drawn to a method of treating disease using family 2 peptidic chemokine modulators. The Applicants also noted that claims 56-58 were erroneously included in this group, and it is claims 53-55 that are drawn to a method of treating disease using family 2 peptidic chemokine modulators. Therefore, Applicant's supplemental election of Group V, drawn to a method of treating disease using family 2 peptidic chemokine modulators, as recited in claims 53-55, is noted and made of record. Because the Applicants did not distinctly and specifically point out the supposed errors

in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement for restriction is therefore deemed proper and is made FINAL.

3. Claims 1-76 are pending. Claims 1-52 and 56-76 are withdrawn as non-elected subject matter. Claims 53-55, drawn to the originally elected method of treating disease using family 2 peptidic chemokine modulators, are the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 9/1/2005 has been fully considered by the Examiner.

Specification

The use of the trademarks TWEEN® (p. 19, line 18; page 32, line 18), COSTAR® (p. 35, line 19), and DIAPHOT® (p. 22, line 7; p. 35, line 5) has been noted in this application. Trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

1. Claims 53-55 are objected to for depending from claim 10, which is drawn to non-elected subject matter. Applicants may re-write claim 53 to include the limitations of base claim 10.

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

1. Claims 53-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating disease mediated by interleukin (IL)-8 by administering a therapeutically effective amount of the peptidic chemokine modulator defined by SEQ ID NO: 64 (BKT-45), does not reasonably provide enablement for methods of treating disease by administering any other peptidic chemokine modulator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims of the instant invention are drawn to a method of treating disease by administration of a peptidic chemokine modulator, and specifically, a family 2 peptidic chemokine modulator as set forth in claim 10. Claim 10 recites a peptidic chemokine modulator comprised of a molecule composed of the amino acids H, P, T, L, R, W, and F, wherein said modulator has at least two neighboring histidines, and wherein said molecule features an overall positive charge. As written, claim 10 is drawn to any polypeptide, of any size, that has H, P, T, L, R, W, and F amino acid residues, provided that the polypeptide contains at least two neighboring histidine residues, and has a positive charge. Because many polypeptides can potentially comprise the recited amino acid residues, including two neighboring histidine residues, and have a positive charge, the breadth of the claims is excessive because the claims are drawn to methods of treating disease by administering an unreasonably large number of potential polypeptides. The specification provides guidance and examples showing that the BKT-45 peptide inhibits interleukin (IL)-8-mediated cell adhesion, and it is known in the art that IL-8 is chemotactic for inflammatory cells and lymphocytes. It is also known that IL-8 mediates several inflammatory conditions, including some types of cancer and autoimmune disease (Mukaida *et al*, The Cytokine Handbook, Ch. 46, pages 1065-1081), as well as various forms of pulmonary/lung disease, and antagonists of IL-8 have been suggested as useful for treatment of

these diseases (Hay *et al*, *Curr. Opin. Pharmacol.* 2001. Vol. 1, pages 242-247). It is unlikely, however, that inhibition of IL-8 would effectively treat all types of malignant cell growth, or all possible bacterial or viral infections. As noted by Hay *et al* (p. 245, 2nd column 3rd full paragraph), inhibition of IL-8 would be useful in conditions where it is the only chemokine involved, and other types of inflammatory/chemotactic chemokines would also have to be inhibited. However, the specification does not provide guidance or examples showing that any other family 2 peptidic chemokine inhibitor that meets the limitations of claim 10 is capable of modulating IL-8, or *any other chemokine*, and is therefore capable of treating any of the diseases recited in claim 55. Because the claims are drawn to administration of a potentially large number of peptides/polypeptides, a person of ordinary skill in the art would not be able to predict which of the many potential peptides/polypeptides could function as chemokine modulators and be effective in treating disease. It would require further, undue experimentation by a skilled artisan to make every possible peptide/polypeptide that meets the limitations of claim 10, and then use these peptides/polypeptides to modulate any chemokine, and ultimately treat disease.

In summary, the breadth of the claims is excessive because they are drawn to methods of treating disease, including *any* type of malignant growth or *any* viral or bacterial infection, with an unreasonably large number of potential peptides/polypeptides. The specification provides guidance and examples showing that the BKT-45 peptide inhibits IL-8-mediated cell adhesion, and may thus be useful for treating diseases known in the art to be dependent upon IL-8-mediated chemotaxis, but does not provide guidance or examples showing that any other peptide/polypeptide is capable of inhibiting IL-8 or any other chemokine. Finally, due to the unpredictability inherent in the art regarding which of the many potential peptides/polypeptides would be capable of inhibiting any chemokine and thus be useful in the treatment of any chemokine-mediated disease, including any type of malignant growth, or any viral or bacterial infection, a person of ordinary skill in the art would require further, undue experimentation in order to make and use any peptide/polypeptide, other than BKT-45, for treating any disease other than those mediated by IL-8.

Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 53-55 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. The claims are drawn to a method of treating disease by administration of a peptidic chemokine modulator comprising the amino acids H, P, T, L, R, W, and F. Due to the open-ended language of claim 10, from which claims 53-55 depend, the claimed peptidic chemokine modulators are not required to have any particular sequence or structure, but are only required to comprise the amino acids H, P, T, L, R, W, and F, have at least two adjacent histidine residues, and have a positive charge. As written, claim 10 reads on any polypeptide with these amino acids, as long as said polypeptide has at least two adjacent histidine residues and possess a positive charge. Furthermore, the claims do not require the peptidic chemokine modulators of the instant invention to have any biological activity other than to "modulate" any chemokine, and the degree or type of modulation is not defined. Thus, the claims are drawn to a large genus of peptides/polypeptides whose structure and function are not adequately described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the peptidic chemokine modulators be comprised of the amino acids H, P, T, L, R, W, and F, have at least two adjacent histidine residues, and have a positive charge. There is no identification of any particular portion of any peptide chemokine modulator that must be conserved in order to maintain function. Although the specification describes the BKT-45 peptide in terms of sequence and function, there are no other examples of any disclosed peptide sequence with a demonstrated function. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

2. The claims of the instant invention are also drawn to treating geni of diseases that have not been adequately described in the specification. Specifically, claim 55 recites a method of treating diseases selected from the group which includes "any type of malignant cell growth", and "acute and chronic bacterial and viral infections". Although it is known in the art that IL-8 contributes to the pathogenesis of some types of cancer, the specification does not adequately describe all possible types of malignant cell growth that can be treated by inhibition of any chemokine. Furthermore, the specification also does not describe the genus of all bacterial diseases that can be treated, as well as the genus of all viral diseases that can be treated by inhibition of any chemokine. There is no common distinguishing factor(s) among all possible types of malignant cell growth, or all types of bacterial or viral infections, that is disclosed that would identify these geni. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed geni of diseases.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 53, as well as dependent claims 54-55, is indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is not clear what controls which of these limitations. See MPEP § 2173.05(h).

2. Claims 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims depend from non-elected claim 10, which recites a peptide chemokine modulator comprising a molecule "composed" of the amino acids H, P, T, L, R, W, and F. The intended meaning of the term "composed" is not clear, and for purposes of examination, has been interpreted as "comprised".

3. Claims 53-55 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to methods of treating disease comprising administering a peptidic chemokine "modulator" that directly "modulates" the activity of a chemokine by "modulation" of binding to the chemokine receptor. The metes and bounds of the phrases "modulator" or "modulates" are not defined by the claims or the specification, which do not define the type or degree of modulation, and thus the claims are indefinite. Additionally, claim 10, from which claims 53-55 depends, also recites a peptidic chemokine "modulator" for "modulating" a biological effect of a chemokine, and would also be rejected as being indefinite if the limitations of this claim were incorporated into the language of claims 53-55. Furthermore, claim 54 recites "modulation of binding to the chemokine receptor", but does not specify if the method is modulating binding of the chemokine to the chemokine receptor, or modulating binding of something else to the receptor.

4. Claim 54 recites the limitation "the chemokines". There is insufficient antecedent basis for this limitation in the claim. Furthermore, claim 54 recites "the chemokines" in the plural form, followed by a recitation of "the chemokine" in the singular form.

5. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a disease selected from a number of conditions, including "a non-optimal immune response". A "non-optimal immune response" is not an art-recognized disease, but rather a feature of a number of possible diseases. Furthermore, "non-optimal" is a relative term, and neither the claims nor the specification defines the context in which an immune response is not "optimal". Thus, the metes and bounds of the term "non-optimal immune response" cannot be determined, and the claim is therefore indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Eriksson *et al* (US 5,840,693). The claims of the instant invention are drawn to a method of treating a disease by administration of a peptidic chemokine modulator, wherein said peptide chemokine modulator comprises a molecule composed of the amino acids H, P, T, L, R, W, and F, and featuring at least two neighboring histidines, and an overall positive charge. The claims are further drawn the method of treatment wherein said peptidic chemokine modulator directly modulates the activity of the chemokine by modulation of binding to the chemokine receptor, and method of treating disease, wherein said disease is from the group set forth in claim 55.

Eriksson *et al* disclose a peptide that is comprised of the amino acids H, P, T, L, R, W, and F, and has two neighboring histidine residues (SEQ ID NO: 13, see F26, L111, P141, H142, H143, R144, W153, T156). Because of the open-ended language of claim 10, which recites a peptidic chemokine modulator *comprising* a molecule *composed* (interpreted as "comprised" – see 35 U.S.C. 112, 2nd paragraph rejection #2 above) of the amino acids H, P, T, L, R, W, and F, the claimed peptidic chemokine modulator is not limited to only these amino acids, and any peptide/polypeptide comprised of these amino acids may meet the limitations of the claim. Thus, SEQ ID NO: 13 of Eriksson *et al*, or the peptide of amino acids 26-156 of SEQ ID NO: 13, meets the limitations set forth in claim 10 for the claimed peptidic chemokine modulator. Regarding an overall positive charge for the molecule, it is noted that the USPTO does not have the facilities for testing the overall charge of the peptide of Eriksson *et al*, and therefore the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Eriksson *et al*. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Eriksson *et al* teaches administration of peptides such as SEQ ID NO: 13 for treating various types of disease characterized by lack of, or reduction in, angiogenesis. Thus, Eriksson *et al* meets the limitations of claim 53 of the instant application. Although Eriksson *et al* does not specifically recite the diseases listed in claim 55, it is known in the art that reduced

angiogenesis is often a characteristic of diabetes, and methods to improve angiogenesis may be useful in the treatment of diabetes (see Kovesdi *et al*, below). Therefore, by teaching administration of a peptide useful for treating conditions characterized by reduced angiogenesis, such as diabetes, Eriksson *et al* meets the limitations of claim 55 of the instant application.

Finally, although Eriksson *et al* does not teach that the peptide of SEQ ID NO: 13 modulates the activity of any chemokine by modulation of binding to the chemokine receptor, it is noted that claim 54 does not specify the degree or type of modulation (i.e. activation, inhibition, etc), and in the absence of evidence to the contrary, it would be expected that the peptide of SEQ ID NO: 13 of Eriksson *et al* would have either a positive or negative effect of some magnitude on the activity of a chemokine. Further, because the USPTO does not have the facilities for testing the effects of the peptide of Eriksson *et al* on chemokine activity or binding of any chemokine to any receptor, the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Eriksson *et al.* See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ. Therefore, the disclosure of Eriksson *et al* also meets the limitations of claim 54 of the instant application.

2. Claims 53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Kovesdi et al (US 2003/0027751 A1). The subject matter of the claims of the instant application is discussed *supra*.

Kovesdi *et al* teaches a peptide, SEQ ID NO: 56, comprised of the amino acids H, P, T, L, R, W, and F, and also contains two neighboring histidine residues. Specifically, Kovesdi et al teaches a peptide set forth in SEQ ID NO: 56 comprising the following residues: F10, R24, L26, H31, H32, T38, and P46. Kovesdi et al also teaches that the amino acids at residues 7, 30, 33, 34, 36, 39, 41, 44, 47, 56, 57, 65, 78, 79, and 81 can be any amino acid, which would include any of the amino acids H, P, T, L, R, W, and F. Because of the open-ended language of claim 10, which recites a peptidic chemokine modulator *comprising* a molecule *composed* (interpreted as "comprised" – see 35 U.S.C. 112, 2nd paragraph rejection #2 above) of the amino acids H, P, T, L, R, W, and F, the claimed peptidic chemokine modulator is not limited to only these amino acids, and any peptide/polypeptide comprised of these amino acids may meet the limitations of the claim. Thus, SEQ ID NO: 56 of Kovesdi *et al* meets the limitations set forth in claim 10 for the claimed peptidic chemokine modulator. Regarding an overall positive charge for the

molecule, it is noted that the USPTO does not have the facilities for testing the charge of the peptide of Kovesdi *et al*, and therefore the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Kovesdi *et al*. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Kovesdi *et al* also teaches administration of peptides such as SEQ ID NO: 56, or comprising SEQ ID NO: 56, for the treatment of various diseases (see paragraph 0179). Thus, Kovesdi *et al* meets the limitations of claim 53 of the instant application. Furthermore, Kovesdi *et al* teaches that peptides such as SEQ ID NO: 56 are useful for promoting tissue growth in conditions such as diabetes and poor circulation (paragraph 0079), thus meeting the limitations of claim 55 of the instant application.

Although Kovesdi *et al* does not teach that the peptide of SEQ ID NO: 56 modulates the activity of any chemokine by modulation of binding to the chemokine receptor, it is noted that claim 54 does not specify the degree or type of modulation (i.e. activation, inhibition, etc), and in the absence of evidence to the contrary, it would be expected that the peptide of SEQ ID NO: 56 of Kovesdi *et al* would have either a positive or negative effect of some magnitude on the activity of a chemokine. Further, because the USPTO does not have the facilities for testing the effects of the peptide of Kovesdi *et al* on chemokine activity or binding of any chemokine to any receptor, the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Kovesdi *et al*. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ. Therefore, the disclosure of Kovesdi *et al* also meets the limitations of claim 54 of the instant application.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER